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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,155	06/01/2001	David J. Anderson	17810-502 CIP CON	3766
30623	7590	03/25/2004		
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			EXAMINER GUCKER, STEPHEN	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/873,155	Applicant(s) ANDERSON ET AL.	
	Examiner Stephen Gucker	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16 is/are rejected.
- 7) ☒ Claim(s) 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/12/01</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody that specifically binds to a neuron-restrictive silencer factor (NRSF) comprising SEQ ID O:40 or SEQ ID NO:50, does not reasonably provide enablement for an antibody that binds to any factor that functions to repress a neuronal phenotype during development. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The mere verbal identification recited in the claims of "...a neuron-restrictive silencer factor (NRSF)" could describe and encompass any and all sequences that may not be related to, and be patentably distinct from, Applicants' disclosed invention of a NRSF protein with a defined sequence as shown in SEQ ID NO: 50. The phrase "... a neuron-restrictive silencer factor (NRSF)" as recited in the claim fail to provide an adequate physical and/or chemical characterization to limit the breadth of the claims to what is enabled in the disclosure. The name of an encoded protein is subject to change and does not represent sufficient characterization. Examples of sufficient characterization would be the amino acid sequence of the encoded protein. Without a method of identifying an isolated protein or factor that relies on objective, quantifiable data rather than the mere recitation of the encoded protein's name, the Applicants could subjectively pick and

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choose what other antibodies to other factors in the art may be encompassed by the claim, and other inventors could not determine if antibodies to factors they discovered were separate and distinct from the antibody to the instant factor without a means of physical characterization. For example, a protein known in the art as REST (Chong et al., PTO-1449, reference H) appears to be the same protein of the instant invention, but obviously does not share the same verbal "name". Furthermore, there may be many different variants of the encoded NRSF protein that exist in nature, such as different species variants, and the instant Application provides insufficient examples or guidance on how to make or use antibodies that would bind to these other variants. The instant Application does not provide sufficient examples or guidance for the skilled artisan to determine without undue experimentation what other antibodies to NRSF protein may be constructed and used in a manner that retains the desired properties of the encoded protein (e.g. transcriptional repression ability).

3. Claim 17 is objected to as being dependent upon claim 16, but would be allowable if written in independent form.

4. No claim is allowed.

5. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone number for this Group is currently (703) 872-9306.

SG

Stephen Gucker

March 22, 2004

Gary L. Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600